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MARTIN D. MOYNIHAN d/b/a PRTSI, INC.
P.O. BOX 16446
ARLINGTON, VA 22215

EXAMINER	
BUCKLEY, AUDREA	
ART UNIT	PAPER NUMBER
1611	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/543,022	SHAPIRA ET AL.	
	Examiner	Art Unit	
	AUDREA J. BUCKLEY	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 November 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 63-87* is/are pending in the application.

4a) Of the above claim(s) *69-73 and 82-87* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,63-68 and 74-81* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *(3) 11/17/2005, 2/20/2008, 8/25/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election of Group I, claims 1 and 63-81, drawn to a composition for potentiating antioxidative activities, in the reply filed on 11/23/2009 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Applicant's election of the classical antacid (claim 68), calcium carbonate (claim 68), polyphenols (claim 74), and flavonol (claim 75) in the reply filed on 11/23/2009 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 69-73 and 82-87 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected composition and a nonelected method for protection from oxidative damage, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 11/23/2009.

Claims 1, 63-68, and 74-81 are examined as these claims read on the elected group and the elected species (see election, 11/23/2009, last three lines before the complimentary close of the letter).

Priority

This application is a 371 of PCT/IL04/00071, filed 01/25/2004. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

The information disclosure statement (IDS) submitted 11/15/2005, 2/20/2008, and 8/25/2008 are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements have been considered by the examiner.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 67 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 67 are vague and indefinite because the metes and bounds of the term "sufficient" are unclear. The instant specification defines the terms "sufficient" and "sufficient dose" as an amount therapeutically effective for exerting any one of its desired activities in vivo (see page 4, lines 23-25). Specifically, in claims 1 and 67, the antacid component is being claimed in a dosage sufficient to elevate the pH in a stomach. By definition, an antacid elevates the pH since a pH elevation from low to

high indicates decreasing acidity and increasing alkalinity. Likewise and further regarding claim 1, an antioxidant, by definition, decreases free radical generation since antioxidants terminate chain reactions by removing free radical intermediates; further, antioxidants inhibit other oxidation reactions since antioxidants themselves are oxidized (i.e., the antioxidant often acts as a reducing agent).

Therefore, the instant specification does not define the subjective term "sufficient" in any limiting way, therefore it is unclear to the skilled artisan as to what would infringe the rejected claims (e.g., see 103 rejections).

Claims 75-78 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 75-78 are vague and indefinite because the metes and bounds of the term "from about" and "to about" are unclear. The instant specification does not define the subjective term "about" in any limiting way, therefore it is unclear to the skilled artisan as to what would infringe the rejected claims (e.g., see 103 rejections). It would be remedial to delete the term "about".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 66, 68, 74, 76, and 79-81 are rejected under 35 U.S.C. 102(b) as being anticipated by Lambert et al. (US 6,284,265 B1, patented Sep. 2001) as evidenced by Handelman et al. ("Antioxidant Capacity of Oat Extracts", J. Agric. Food Chem., 1999, 47, 4888-4893).

Regarding claims 1, 66, 68, and 81, Lambert et al. teach an antacid formulation comprising an antacid or mixture of antacids, oil, an antioxidant, and a carrier (see abstract, in particular). In a particular formulation, the embodiment comprises 10.0% dihydroxy-aluminum-sodium-carbonate, 10% aluminum phosphate, 2.75% dicalcium phosphate, and 0.7% calcium carbonate, all antacid components totaling 23.45% by mass of the total formulation further comprising 70.45% by mass of a carrier, 6.0% soybean oil (a lubricant), and 0.1% of the antioxidant ethoxyquin (see column 3, lines 32-40). In terms of the carrier, Lambert et al. teach that the 70.45% carrier is broken down into 30.45% ground wheat, 20.0% spray dried whey, and 20% steam rolled oats, which inherently comprise plant-derived antioxidants and phenol derivatives as evidenced by Handelman et al. Regarding claim 74, Handelman et al. teach the antioxidant capacity of oat extracts wherein several classes of compounds with antioxidant activity, including vitamin E tocols, flavonoids, and non-flavonoid phenolic acids, have been identified in oat (see page 4888, Introduction, paragraph 1). Since rolled oats comprise 14.1% (20% of 70.45%) of the total antacid formulation, this embodiment of Lambert et al. reads on instant claim 76. As to claims 79 and 80,

Lambert et al. teach that the antacid formulation can be pelletized for oral administration (see column 3, lines 45).

Therefore, Lambert et al. anticipate the content and limitations of the instant claims as outlined above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 63, 64, 66-68, 74, 76, and 79-81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lambert et al. (US 6,284,265 B1, patented Sep. 2001) as evidenced by Handelman et al. ("Antioxidant Capacity of Oat Extracts", J. Agric. Food Chem., 1999, 47, 4888-4893).

Regarding claims 1, 66, 68, and 81, Lambert et al. teach an antacid formulation comprising an antacid or mixture of antacids, oil, an antioxidant, and a carrier (see abstract, in particular). In a particular formulation, the embodiment comprises 10.0% dihydroxy-aluminum-sodium-carbonate, 10% aluminum phosphate, 2.75% dicalcium phosphate, and 0.7% calcium carbonate, all antacid components totaling 23.45% by mass of the total formulation further comprising 70.45% by mass of a carrier, 6.0% soybean oil (a lubricant), and 0.1% of the antioxidant ethoxyquin (see column 3, lines 32-40). In terms of the carrier, Lambert et al. teach that the 70.45% carrier is broken down into 30.45% ground wheat, 20.0% spray dried whey, and 20% steam rolled oats, which inherently comprise plant-derived antioxidants and phenol derivatives as evidenced by Handelman et al. Regarding claim 74, Handelman et al. teach the antioxidant capacity of oat extracts wherein several classes of compounds with antioxidant activity, including vitamin E tocols, flavonoids, and non-flavonoid phenolic acids, have been identified in oat (see page 4888, Introduction, paragraph 1). Since rolled oats comprise 14.1% (20% of 70.45%) of the total antacid formulation, this embodiment of Lambert et al. reads on instant claim 76. As to claims 79 and 80,

Lambert et al. teach that the antacid formulation can be pelletized for oral administration (see column 3, lines 45).

As to claims 63 and 64, it is the examiner's position that the capability of decreasing free radical and peroxide generation as in claim 63 and the ability to decrease at least two fold concentration of free radicals and peroxides as in claim 64 are result effective variables because changing them clearly will affect the type of product obtained. See MPEP 2144.05(b). Case law holds that "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." See In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

In view of this, it would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize appropriate quantities of the antioxidant and antacid components in order to control the potency and efficacy of the antacid formulation, including those quantities within the scope of the present claims, so as to produce desired end results. Therefore, the content and the limitations of the instant claims are obvious over Lambert et al. as evidenced by Handelman et al.

Claim 67 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lambert et al. (US 6,284,265 B1, patented Sep. 2001) as evidenced by Handelman et al. ("Antioxidant Capacity of Oat Extracts", J. Agric. Food Chem., 1999, 47, 4888-4893) as applied to claims 1, 63, 64, 66-68, 74, 76, and 79-81 above, and further in view of Grimberg (US 5,667,802, patented Sep. 1997).

The teachings of Lambert et al. are delineated above.

As to claim 67, Lambert et al. do not quantify the reduction of pH as a result of antacid administration.

However, Grimberg teaches an antacid composition employing a variety of antacids such as magnesium oxide. Grimberg studies the change in pH as a function of time upon administration of the antacid formulation. For example, Figure 7 illustrates the pH changes with magnesium hydroxide, and it is noted that the pH unit is increased by at least one pH unit as required by the instant claim.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to quantify the pH increase as a measure of efficacy of the antacid formulation and to formulate an antacid composition having the pH change deemed effective as taught by Grimberg. The skilled artisan would have been motivated to do so in order to more fully characterize the antacid properties and efficacy in the formulations of Lambert et al. as taught by Grimberg.

Claims 65, 75, 77, and 78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lambert et al. (US 6,284,265 B1, patented Sep. 2001) as evidenced by Handelman et al. ("Antioxidant Capacity of Oat Extracts", J. Agric. Food Chem., 1999, 47, 4888-4893) as applied to claims 1, 63, 64, 66-68, 74, 76, and 79-81 above, and further in view of Howard et al. (US 6,099,854, patented Aug. 2000).

The teachings of Lambert et al. are delineated above.

Lambert et al. does not limit the antioxidant component to one which is a polyphenol selected from the flavonol group in the specified quantity.

Regarding claims 65 and 75-77, Howard et al. teach a flavonol-containing composition wherein at least 25% of the composition includes polyphenols and at least 1.0% is flavonol (see abstract, in particular), both of which are plant-derived (see column 6, lines 1-3; see also, column 25, lines 46-50). Howard et al. more preferably teaches that the plant derived material comprises at least 35% polyphenols or more preferably at least 45% polyphenols (see column 5, lines 65-67). As to claim 78, Howard et al. do not teach the polyphenol content necessarily as present in the instantly claimed quantity, although the ranges overlap. MPEP 2144.05 addresses as follows the obviousness of overlapping ranges:

> Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).
>
> In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a *prima facie* case of obviousness exists. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to include the polyphenol and flavonol plant-derived antioxidants as disclosed in the teaching of Howard et al. in the formulation of Lambert et al., which also teaches the benefits of the antioxidant component. All these formulations are to be taken orally as a health benefit; Lambert et al. teaches that an antioxidant generally benefits the antacid formulation since the antioxidant functions to

prevent oxidation and breakdown of certain components of the composition prior to consumption (see column 3, lines 9-12). Lambert et al. generally teaches the benefits of antioxidants but teaches only one example; as such, the skilled artisan would have been motivated to look to the teaching of Howard et al. which discloses consumable antioxidants and further teaches the added health benefits of these particular polyphenol antioxidants. Further, the skilled artisan would have been motivated to implement the polyphenol antioxidants for the reasons deemed desirable by Howard et al., including the convenience of obtaining the active agent (see column 7, lines 14-16), the known health benefits of polyphenols (i.e., desirable antioxidant activity in LDL) (see column 13, lines 4-7).

Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AUDREA J. BUCKLEY whose telephone number is (571)270-1336. The examiner can normally be reached on Monday-Thursday 7:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571) 272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/AJB/

/David J Blanchard/
Primary Examiner, Art Unit 1643